REMARKS

Reconsideration of the rejections set forth in the Office Action mailed November 30, 2004, is respectfully requested. Applicants have amended claims 1 and 6, and have added new claims 11, 12, and 13.

Rejection of Claims 1, 5, 9 and 10 under 35 U.S.C. §102(e)

The Examiner rejected claims 1, 5, 9 and 10 under 35 U.S.C. §102(e) for allegedly being anticipated by Alferness *et al.* (US 6,293,951). Applicants have amended claim 1 and respectfully traverse this rejection with respect to claims 1, 5, 9 and 10.

Anticipation under 35 U.S.C. §102(e) requires the disclosure in a single reference that teaches each element of the claim under consideration. All limitations of the claim must be found in the reference. Moreover, it is incumbent on the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference. Applicants respectfully submit that Alferness fails to anticipate claims 1, 5, 9, and 10.

Claim 1

Instant claim 1 as amended herein is directed to a method for lung volume reduction comprising:

> deploying an obstructive device through an access catheter in a lung passageway to a lung tissue segment; and
>
> aspirating the segment through the deployed obstructive device to at least partially collapse the lung segment.

Alferness fails to teach or suggest several elements of claim 1. For example, Alferness fails to show the step of deploying an obstructive device through an access catheter and then aspirating a lung segment through the deployed obstructive device. In rejecting claim 1, the Examiner indicated that the catheter (70) in Alferness

corresponds to the obstructive device of claim 1. However, unlike claim 1, the catheter (70) of Alferness is not deployed through an access catheter – it **is** the access catheter. It is not physically possible for an obstructive device comprised of a catheter to be deployed "through" itself. Thus, Alferness fails to teach or suggest deploying an obstructive device comprised of a catheter (70) through an access catheter into a lung passageway. Moreover, Alferness makes no mention of deploying the catheter (70) through a separate access catheter.

Furthermore, the obstructing member (90) of Alferness cannot correspond to the obstructive device cited in claim 1. This is because claim 1 further recites "aspirating the [lung] segment through the deployed obstructive device." As discussed below, Alferness fails to teach or suggest aspiration of the lung through the obstructing member (90). Rather, aspiration is performed prior to inserting the obstructing member (90) into the lung.

Because Alferness fails to teach each and every element of claim 1, applicants respectfully submit that claim 1 is patentably distinct from Alferness. Applicants respectfully submit that the Examiner should withdraw the rejection of claim 1.

Claim 5

Claim 5 recites a system for obstructing a lung passageway to a lung tissue segment comprising:

> an access catheter having a proximal end, a distal end, and at least one lumen extending therethrough, and
>
> an obstruction device deployable within the lung passageway having an inlet port adapted for aspirating the lung tissue segment through the inlet port,
>
> wherein the obstruction device is introduceable by the access catheter.

Alferness fails to teach or suggest several elements of claim 5. For example, Alferness fails to teach or suggest an obstruction device having an inlet port adapted for aspirating a lung tissue segment through the port. In the office action, the examiner compared the inflatable sealing member (74) to the obstructive device of claim 5 and indicated that the inflatable sealing member (74) has an inlet port adapted for aspirating a lung tissue segment through the port.

However, the inflatable sealing member (74) has no such inlet port adapted for aspirating a lung tissue segment through the port. In Alferness, the inflatable sealing member (74) does have an inlet port that communicates with a minor channel (84) in the catheter 70. ("As may be seen in FIG. 4, the catheter 70 includes a minor channel (84) which is utilized for inflating the inflatable member 74." Alferness, 5:18-21.) However, the inlet port between the inflatable sealing member (74) and the minor channel 84 is not "adapted for aspirating the lung tissue segment through the inlet port". To the contrary, the inlet port of inflatable sealing member (74)/minor channel (84) is entirely enclosed by the inflatable sealing member (74) and is not in communication with the lung tissue segment. Thus, aspiration through the minor channel (84) would not result in fluid flow out of the lung tissue segment. Rather, this would result in aspiration, deflation and fluid flow out of the inflatable sealing member (74).

Applicants note that the catheter (70) in Alferness has a main channel (82) through which a vacuum in a lung portion is pulled. (Alferness, 5:18-20.) However, the inflatable sealing member (74) does not have an inlet port that communicates with the main channel (82). Rather, the main channel is entirely walled off from the inflatable sealing member (74) with no inlet port therebetween. Indeed, it would be impractical to form an inlet port between the inflatable sealing member (74) and the main channel (82), as such an inlet port would permit air to flow out of the inflatable sealing member (74) during inflation via the minor channel (84).

Thus, Alferness fails to teach each and every element of claim 5. Applicants respectfully submit that claim 5 is patentably distinct from Alferness and that the rejection of claim 5 should be withdrawn.

Claim 9

Claim 9 recites a method for lung volume reduction comprising:

> releasing an obstructive device in a lung passageway to a lung tissue segment; and
>
> aspirating the segment through the released obstructive device to at least partially collapse the lung segment.

Alferness fails to teach or suggest several elements of claim 9. For example, Alferness fails to teach or suggest the step of "releasing an obstructive device in a lung passageway to a lung tissue segment." In the office action, the Examiner compares the inflatable sealing member (74) in Alferness to the obstructive device of claim 9. However, the inflatable sealing member (74) is not and can not be "released" in a lung passageway to a lung tissue segment. The Merriam-Webster dictionary defines "release" as "to let go." The inflatable sealing member (74) in Alferness is fixedly attached to the catheter (70). Thus, it is not physically possible to release or "let go" of the inflatable sealing member (74) in a lung passageway. Rather, the inflatable sealing member (74) always remains attached to the distal end of the access catheter (70). Therefore, Alferness fails to teach or suggest releasing an obstructive device in a lung passageway as in claim 9.

Because Alferness fails to teach each and every element of claim 9, applicants respectfully submit that claim 9 is patentably distinct from Alferness.

Claim 10

Claim 10 recites a method for lung volume reduction comprising:

> deploying an obstructive device comprising a valve in a lung passageway to a lung tissue segment; and
>
> aspirating the segment through the deployed obstructive device to at least partially collapse the lung segment.

Alferness fails to teach or suggest several steps of claim 10. For example, Alferness fails to teach or suggest aspirating a lung segment through a deployed obstructive device comprised of a valve. Although Alferness describes deploying an obstructing member 90 comprised of a valve in a lung passageway to a lung tissue segment, Alferness fails to teach or suggest aspirating the lung segment through the obstructing member 90. Rather, Alferness teaches aspirating the lung **prior to** inserting the obstructing member 90 in the lung. Thus, aspiration does not occur through the obstructing member 90 in Alferness.

In column 5, lines 23 – 28, Alferness describes how the lung portion is aspirated: "[A] vacuum is pulled through the main channel 82 of the catheter 70 to pull the vacuum in lung portion 6. ... [T]he lung portion 66, due to the vacuum pulled by the pump 80 and catheter 70 of FIG. 3, has collapsed from its initial state." In column 5, lines 29 – 33, Alferness then describes deployment of the obstructing member (after vacuum is pulled in the lung): "With the lung portion 66 thus collapsed, and while the lung portion 66 is collapsed, an obstructing member 90 is guided through the main channel of the conduit 70..." Further, in column 5, lines 43 – 46, Alferness discloses that "[t]he sealing member 90 has expanded upon placement in the air passageway 50 to seal the air passageway 50. This causes the lung portion 66 to be maintained in a permanently collapsed state" Thus, aspiration and partial collapse of the lung segment in Alferness

does not occur through a deployed obstructive device comprising a valve as recited in claim 10 herein. Aspiration and partial collapse of the lung segment in Alferness occurs **prior to** deployment of an obstructive device comprising a valve. The obstructive device comprising a valve disclosed in Alferness is deployed after the lung portion is collapsed in order to maintain the collapsed state.

Because Alferness does not teach each and every step of claim 10, applicants respectfully submit that claim 10 is patentably distinct from Alferness. Applicants respectfully submit that the Examiner should withdraw the rejection of claim 10.

Rejection of Claim 6 under 35 U.S.C. §103(a)

The Examiner rejected claim 6 under 35 U.S.C. §103(a) for allegedly being unpatentable over Alferness, in view of Daniel *et al.* (5,980,455). Applicants have amended claim 6 herein and respectfully traverse this rejection.

In order to establish a *prima facie* case of obviousness, there must be evidence, preferable a teaching, suggestion, incentive or inference from the cited art or in the form of generally available knowledge that one of ordinary skill in the art would have been led to modify the relevant teaching to arrive at what is claimed. The prior art must provide a motivation whereby one of ordinary skill in the art would have been led to do that which the applicant has done. In addition, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.

Claim 6 recites a kit comprising:

> an obstruction device deployable within a lung passageway; and
>
> instructions for use according to a method of lung volume reduction comprising:
>
> deploying an obstructive device through an access catheter in a lung passageway to a lung tissue segment; and

aspirating the segment through the deployed obstructive device to at least partially collapse the lung segment.

Claim 6 includes instructions for use that include deploying an obstructive device **through an access catheter** in a lung passageway. In rejecting claim 1, the Examiner compared the access catheter (74) in Alferness to the obstructive device in claim 1. As described in above with respect to claim 1, in Alferness the catheter (70) is not deployed through an access catheter – it **is** the access catheter. Alferness fails to teach or suggest deploying an obstructive device through an access catheter in a lung passageway to a lung tissue segment. In addition, Daniels fails to provide the missing teaching.

Applicants respectfully submit that Alferness and Daniel, both alone and in combination, fail to teach or suggest the kit of claim 6 and, therefore, claim 6 is patentably distinct from Alferness and Daniel.

New Claims

Claims 11, 12 and 13 have been added by way of this amendment. The claims do not add new matter and are fully supported by the specification.

Claim 11 further limits the method of claim 9. Applicants respectfully submit that new claim 11 is patentably distinct from Alferness and Daniel.

New claims 12 and 13 recite the steps of deploying an obstructive in a lung passageway to a lung tissue segment and aspirating the segment through the deployed obstructive device. Applicants submit that the examiner should interpret the term "deploying" in claim 1 in view of the specification of the instant application. As described in the specification and the drawings, e.g., page 6, lines 8 – 22 and Figure 2, the term "deploying" an obstructive device in a lung passageway means to release the obstructive device in a lung passageway such that the obstructive device is not attached to a delivery device. Thus, an obstructive device is released once it is not attached to a delivery device or other device used in deploying the obstructive device. Alferness fails

to show such an obstructive device. The inflatable sealing member (74) in Alferness cannot be "deployed" as in claims 12 and 13, as the balloon is fixedly attached to the delivery catheter. In addition, the obstructing member 90 cannot correspond to the obstructive device of claims 12 and 13, as aspiration is not performed through the obstructing member 90.

Conclusion

Applicants respectfully submit that the pending claims are now in condition for allowance and respectfully request the same. If the Examiner has any questions regarding the foregoing, he is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,

Date: May 23, 2005

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